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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/740,255	12/18/2003	Michael John Rutter	CHM-019	1904
38155	7590	04/26/2005	EXAMINER	
HASSE GUTTAG & NESBITT LLC 7550 CENTRAL PARK BLVD., MASON, OH 45040			MITCHELL, TEENA KAY	
			ART UNIT	PAPER NUMBER
			3743	

DATE MAILED: 04/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/740,255

Applicant(s)

RUTTER, MICHAEL JOHN

Examiner

Teena Mitchell

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 2/4/05.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

The drawing objection in the last office action has been removed because applicant has changed the claim language with respect to claim 5.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beran (4,516,293).

Beran in an adjustable collar (10) for a nasal or oral endotracheal tube, discloses:

- a smooth first surface (14) for contacting the skin of a patient using the endotracheal tube,
- a support section (26) attached to the first surface (14), and
- a band (28) attached to the support section (26) comprising flexible domes (62) that compress against the tube (12) and grip it when the collar is secured around the tube (Fig. 4) without significantly compressing the tube and restricting air flow (inasmuch as the tube of

Beran is not restricting air flow, the domes do not **significantly compress** the tube, because applicant has not defined what is actually meant by "without significantly compressing", therefore while the domes of Beran may deform the tube, the domes do not significantly compress the tube because air can still flow through the tube).

The difference between Beran and claim 1 is the limitation of the domes having a height above the surface of the band of from about 0.3 to about 3 mm. At the time the invention was made, it would have been an obvious matter of design consideration to a person of ordinary skill in the art to have the height of the domes above the surface of the band of from about 0.3 to 3 mm because applicant has not disclosed that having the domes height above the surface of the band of from about 0.3 to about 3 mm solves any stated problem, provides any advantage, or is used for any particular purpose. Moreover, it appears that the domes would have performed equally as well with the dome height at any other size, including the dome height of Beran because the domes of Beran hold the tube in place and are still able to provide air flow through the tube. Accordingly, the use of the domes height above the surface of the band of from about 0.3 to 3 mm are deemed to be a design consideration which fails to patentably distinguish over the prior art of Beran.

The difference between Beran and claim 2 is the collar being made of a semi-rigid, non-irritating plastic material. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have the collar made of a semi-rigid, non-irritating plastic material, since it has been held to be within the general skill of a worker

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in the art to select a known material on the basis of its suitability for the intended use as a matter of design consideration (In re Leshin, 227 F.2d 197, 125 USPQ 416) and because in the medical field it is known to use semi-rigid, non-irritating materials for cannula holding devices because the material is durable and non-irritating material is used because many patient's using the device often have the tubes in for extended periods of time and therefore a non-irritating material helps maintain skin integrity and lessen skin breakdown.

With respect to claims 3, 6, and 10 note rejection of claim 2 above.

With respect to claim 4, Beran discloses the collar for use with a nasal endotracheal tube (Col. 1, lines 17-23), wherein said collar is tapered in the region where it contacts the endotracheal tube.

With respect to claim 5, Beran discloses the collar is shaped so that it holds the endotracheal tube at an angle relative to the skin between the patient's nose and upper lip whereby the tube is closer to the skin proximally than it is distally; it would be inherent that the collar of Beran meets the claimed functional limitations as the collar supports the tube prior to insertion into nasal or oral cavity.

With respect to claims 7 and 11, Beran discloses a retainer strip underlies the domes (44), as for the strip being a plastic note rejection of claim 2 above.

With respect to claim 8, Beran discloses wherein the strip comprises a lock at one end (32) and a belt at the other end (see illustration of Fig. 2 below).

With respect to claim 9, Beran discloses an adjustable collar (10) comprising:

- a smooth first surface (14) for contacting the skin of the patient,

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- a support section (26) attached to the first surface (14), and
- a band (28) attached to the support section (26) comprising flexible domes (62) that compress against the tube (12) and grip it when the collar is secured around the tube (12, Fig. 4), without significantly compressing the tube and restricting air flow (inasmuch as the tube of Beran is not restricting air flow, the domes do not **significantly compress** the tube, because applicant has not defined what is actually meant by without significantly compressing, while the domes of Beran may deform the tube, the domes do not significantly compress the tube because air can still flow through the tube) and
- lateral extensions (18-21) from the collar for securing the collar to the head of the patient.

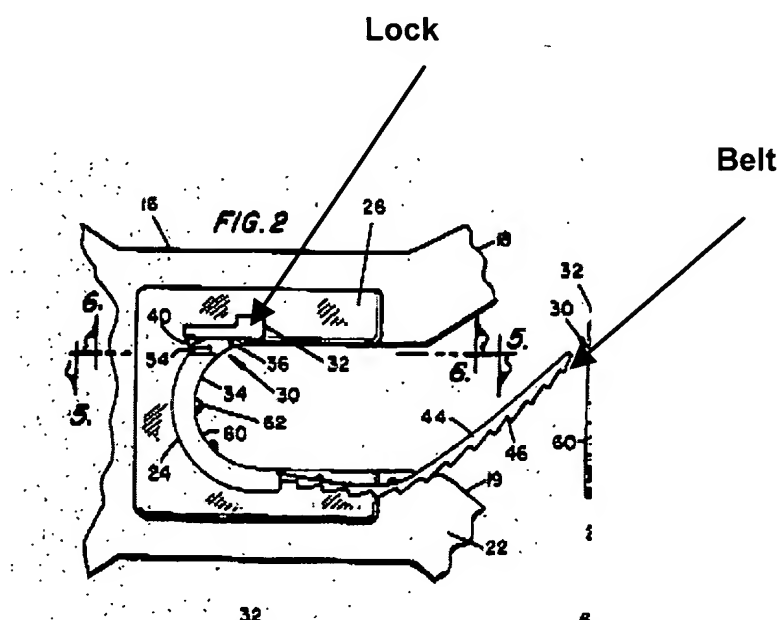
The difference between Beran and claim 9 is the limitation of the domes having a height above the surface of the band of from about 0.3 to about 3 mm. At the time the invention was made, it would have been an obvious matter of design consideration to a person of ordinary skill in the art to have the height of the domes above the surface of the band of from about 0.3 to 3 mm because applicant has not disclosed that having the domes height above the surface of the band of from about 0.3 to about 3 mm solves any stated problem, provides any advantage, or is used for any particular purpose. Moreover, it appears that the domes would have performed equally as well with the dome height at any other size, including the dome height of Beran because the domes of Beran hold the tube in place and are still able to provide air flow through the tube.

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Accordingly, the use of the domes height above the surface of the band of from about 0.3 to 3 mm are deemed to be a design consideration which fails to patentably distinguish over the prior art of Beran.

With respect to claim 12, Beran discloses wherein the lateral extensions have a bi-lobed appearance (18-21).

With respect to claim 13, Beran discloses wherein the lateral extensions (18-21) have a smooth surface that contacts the patient's skin (at 14).



With respect to claim 14, Beran discloses an adjustable collar (10) comprising:

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- a smooth first surface (14) for contacting the skin of the patient,
- a support section (26) attached to the first surface (14), and
- a band (28) attached to the support section (26) comprising flexible domes (62) that compress against the tube (12) and grip it when the collar is secured around the tube (12, Fig. 4), without significantly compressing the tube and restricting air flow (inasmuch as the tube of Beran is not restricting air flow, the domes do not **significantly compress** the tube, because applicant has not defined what is actually meant by without significantly compressing, while the tube of Beran may deform the tube, the domes do not significantly compress the tube because air can still flow through the tube) and
- lateral extensions (18-21) from the collar for securing the collar to the head of the patient.

The difference between Beran and claim 14 is the limitation of the domes having a height above the surface of the band of from about 0.3 to about 3 mm. At the time the invention was made, it would have been an obvious matter of design consideration to a person of ordinary skill in the art to have the height of the domes above the surface of the band of from about 0.3 to 3 mm because applicant has not disclosed that having the domes height above the surface of the band of from about 0.3 to about 3 mm solves any stated problem, provides any advantage, or is used for any particular purpose. Moreover, it appears that the domes would have performed equally as well with the dome height at any other size, including the dome height of Beran because the domes

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of Beran hold the tube in place and are still able to provide air flow through the tube. Accordingly, the use of the domes height above the surface of the band of from about 0.3 to 3 mm are deemed to be a design consideration which fails to patentably distinguish over the prior art of Beran.

With respect to the limitation of at least one strap attached to the lateral extensions Beran discloses holders include an adhesive surface or other attachment means including straps and hook and fabric arrangements (Col. 1, lines 49-52). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the adhesive for strap attachment means as disclosed by Beran.

With respect to claim 15, Beran discloses that hook and fabric arrangements are known therefore it would have been obvious to one of ordinary skill in the art to have at least one strap of hook and loop refastenable material as such material is well known in the art (Col. 1, lines 49-52).

With respect to claim 16, it would be inherent that the at least one lateral strap connects the at least one strap attached to the lateral extensions (18-21).

With respect to claim 17, note rejection of claim 2 above.

With respect to claim 18, Beran discloses wherein the lateral extensions (18-21) have a bi-lobed appearance.

With respect to claim 19, Beran discloses a retainer strip (44) underlies the domes (62), as for the limitation of being plastic note rejection of claim 2 above.

With respect to claim 20, Beran does not disclose two straps. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have two straps, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art and the use of two straps would provide additional securing means to a user.

Response to Arguments

Applicant's arguments filed 2/4/05 have been fully considered but they are not persuasive. Applicant argues that Beran does not disclose that the domes compress and grip the tube without significantly compressing the tube and restricting airflow. The domes of Beran "merely distort its shape in small degree" because applicant has not defined what is actually meant by "**without significantly compressing the tube**" and the tube of Beran distorts the tube shape in small degree but still allows for air flow through the tube, therefore the domes of Beran are readable upon the limitations of "without significantly compressing the tube and restricting airflow".

With respect to the arguments of the specific height of the domes of Beran, note rejection of claims 1, 9, and 14 above. The domes of Beran perform the function of holding the tube in place, therefore based on the size of tube being used (i.e., such as in a NICU, pediatric, adult) different domes height would be required to hold the tube, as a tube for a newborn would require a smaller dome height as the tube for a newborn is smaller than one used for a pediatric patient. Therefore, one of ordinary skill in the art could arrive at the claimed dome height based on the intended use of the tube (i.e.,

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NICU, pediatric, or adult) use. Therefore the claimed height limitations does not patentably distinguish over the prior art of Beran.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

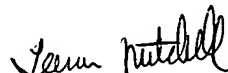
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teena Mitchell whose telephone number is (571) 272-4798. The examiner can normally be reached on Monday-Friday however the examiner is on a flexible schedule.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on (571) 272-4791. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Teena Mitchell
Examiner
Art Unit 3743